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10/065,278

09/30/2002

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EXAMINER

DAWSON, GLENN K

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

05/18/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/065,278

Applicant(s)

LEUNG ET AL.

Examiner

Glenn K. Dawson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 17-31, 34, 35 and 37-152 is/are pending in the application.
- 4a) Of the above claim(s) 21-31, 35, 37-54, 67-78, 85-140 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-20, 34, 55-66, 79-84 and 141-152 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-20,34,141-144,147 and 150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alcamo-3123077 in view of Granger-5123911.

Alcamo discloses a barbed suture with helically positioned barbs. However, the ratio of the suture diameter to needle diameter is not disclosed. Additionally, the barbs being in a twist cut multiple spiral disposition is not disclosed. However, the examiner notes that the twist cut is really a product-by-process limitation. Once the cuts are made after the suture has been twisted, the suture is unwound. The resulting pattern of the cuts is merely a multiple spiral. Since Alcamo discloses a suture with barbs which are in multiple spirals, this limitation is met. As for the specific spirality angle, as these were afforded no particular significance in the specification, were not disclosed as solving any particular problem or being for any particular purpose, the examiner contends that such angles would be obvious design choices, as the applicant's invention would work equally as well with the undisclosed spirality angle of the Alcamo's barbs.

Granger discloses that it was known to attach sutures to suturing needles; wherein the diameter of the needle is equal to the diameter of the suture. This ratio would fall within the claimed ratio. It would have been obvious to have attached the barbed suture of Alcamo to an equal diameter suture needle, in order to facilitate the attachment process and to produce a stronger suture/needle combination which can easily traverse through tissue. As for the range of the ratio being between 3:1 to about 1.47:1, the applicant failed to disclose that the lower limit being 1.47:1 was in any way critical, and did not solve any particular problem or solve any particular purpose relative to ratios between 1.47:1 and 1:1. Ganger indicated that normally the needle diameter would be larger than that of the suture and therefore, ratios above 1:1 were disclosed, however, what the exact ratio is was not disclosed. The examiner contends that one would have assumed that a ratio of about 1.47:1 would have produced a similar result to that of around 1:1 and therefore this lower limit on the range would have been considered an obvious design choice.

Claims 55-66 and 79-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alcamo-3123077 in view of Granger-5123911, as applied above, and further in view of Buncke-5931855.

Alcamo as modified by Granger makes obvious the invention as claimed with the exception of the suture materials. Buncke, discloses the claimed suture materials. It would have been obvious to have made the Alcamo/Granger suture out of the suture materials disclosed by Buncke, as these materials to tailor the suture to the procedure...

e.g. for certain procedures, it would be desirable for the suture to be non-absorbable and others it would be more desirable for the sutures to be absorbable.

Claims 17-20,34,55-66,79-84, 141-144,147 and 150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke-5931855 in view of Granger-5123911.

Buncke discloses a barbed suture with helically positioned barbs. The suture is formed of absorbable or non-absorbable material. However, the ratio of the suture diameter to needle diameter is not disclosed. Additionally, the barbs being in a twist cut multiple spiral disposition is not disclosed. However, the examiner notes that the twist cut is really a product-by-process limitation. Once the cuts are made after the suture has been twisted, the suture is unwound. The resulting pattern of the cuts is merely a multiple spiral. Since Buncke discloses a suture with barbs which are in multiple spirals, this limitation is met. As for the specific spirality angle, as these were afforded no particular significance in the specification, were not disclosed as solving any particular problem or being for any particular purpose, the examiner contends that such angles would be obvious design choices, as the applicant's invention would work equally as well with the undisclosed spirality angle of the Buncke's barbs.

Granger discloses that it was known to attach sutures to suturing needles; wherein the diameter of the needle is equal to the diameter of the suture. This ratio would fall within the claimed ratio. It would have been obvious to have attached the barbed suture of Buncke to an equal diameter suture needle, in order to facilitate the

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attachment process and to produce a stronger suture/needle combination which can easily traverse through tissue.

As for the range of the ratio being between 3:1 to about 1.47:1, the applicant failed to disclose that the lower limit being 1.47:1 was in any way critical, and did not solve any particular problem or solve any particular purpose relative to ratios between 1.47:1 and 1:1. Ganger indicated that normally the needle diameter would be larger than that of the suture and therefore, ratios above 1:1 were disclosed, however, what the exact ratio is was not disclosed. The examiner contends that one would have assumed that a ratio of about 1.47:1 would have produced a similar result to that of around 1:1 and therefore this lower limit on the range would have been considered an obvious design choice.

Claims 145,146,148,149,151 and 152 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alcamo-3123077 in view of Granger-5123911, (or Buncke-5931855 in view of Granger-5123911), as applied to the claims above, and further in view of Coplan-3918455.

Alcamo or Buncke as modified by Granger make obvious the invention as claimed with the exception of the suture cross-sectional shape being non-round. Coplan discloses that it was known to manufacture sutures to have other shaped sutures. It would have been a mere obvious design choice to have manufactured the sutures of Alcamo or Buncke as modified by Granger in a non-round shape as taught by Coplan.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the cross-sectional shapes of the suture being non-round, and in particular that claimed in claims 145, 146, 148, 149, 151 and 152 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.



***Response to Arguments***

Applicant's arguments filed 03-08-07 have been fully considered but they are not persuasive.

Applicant argues that the claimed ratio of the Needle to the suture is not disclosed by Granger. This is not found persuasive. In col. 7 lines 13-21 it is clearly disclosed to attach sutures of equal diameter to suture needles together. This ratio is 1:1, and clearly falls within that claimed by the applicant. M.P.E.P clearly states in 2131.03 I- that a specific example that is disclosed in the prior art that falls within a claimed range anticipates the range. Therefore a specific example of 1:1 which falls within the range of 3:1 or less anticipates this range. This fact pattern is not similar to Atofina since a specific example is disclosed in the prior art which is within the claimed range. Applicant states that a ratio of needle to suture diameter of less than one is outside the scope of the invention. This statement is incorrect. Not only does the claim allow for larger sutures than needles (a needle to suture ratio of 0.5:1 is less than 3:1 and therefore within the claimed range), but the applicant's specification in paragraphs 182 and 185 state that this ratio can be down to less than 1:1 such as 0.5:1. Claim 43 (withdrawn) even claims a needle smaller than the suture. The claims cover any suture and needle combination where the suture is larger than the needle up to where the needle is 3 times larger than the suture.

As stated before, once applicant's suture is unwound, the disposition of the spirals would be similar if no the same as the prior art. The fact that the prior art's sutures would have additional barbs in between the barbs which are aligned in a spiral

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fashion is not germane to the issue. Applicant's claims are couched in the open transitional phrase of "comprising" and therefore, the prior art suture barbs can have additional barbs to those spirally disposed. As previously contended, since the barbs of the prior art can have a spiral line connecting barbs at positions along the longitudinal axis of the suture, the claim limitations are met. There is every reason to believe that the prior art was modified as suggested that it would work equally as well as the applicant's.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Glenn K Dawson  
Primary Examiner  
Art Unit 3731

Gkd  
11 May 2007